AR201-13964

To: NCIC OPPT/DC/USEPA/US@EPA, Rtk Chem/DC/USEPA/US@EPA
cc: Richard Hefter/DC/USEPA/US@EPA, STEPHEN_LONGACRE@fmc.com

Subject: HPV Challenge Program, AR-201 - Registration Number:

FMC Corporation actively supports the EPA HPV Challenge Program, AR-201. Attached is FMC's response to the EPA comments posted on July 19, 2002 regarding our December 28, 2001 submission to the RTK HPV Challenge Program of the test plan and robust summaries for the single chemical:

Cyclopropanecarboxylic acid, 3(2,2-dichloroethenyl)-2,2-dimethyl-, methyl ester -- CAS No. 61898-95-1

The attached files include FMC's Response to EPA comments, a Revised Test Plan and Revised Robust Summaries. Revisions made to the test plan and robust summaries appear in red.

Please contact me if you have comments or questions regarding FMC's submission.

Sincerely,

Natalie Rutherford
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FMC Corporation
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- MDVE-RevTestPlan.doc
- MDVE Comments.doc
- MDVE-RevSummaries.doc

FMC Response to EPA Comments on the CYCLOPROPANECARBOXYLIC ACID, 3(2,2-DICHLOROETHENYL)-2,2-DIMETHYL-, METHYL ESTER Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

EPA Comment

EPA agrees with the submitter's proposal to conduct a partition coefficient test. Adequate existing data are available for the other endpoints.

FMC Response

No response.

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

EPA Comment

EPA agrees with the submitter's proposal to conduct a biodegradation test. Adequate existing data are available for the other endpoints. However, the submitter needs to provide the in-put values for the fugacity calculation.

FMC Response

The robust summary has been revised to include all input values for the fugacity calculation. The only user input in the model is the structure of the molecule. All other input values are calculated by EPI-WIN. An explanation of the fugacity model used in EPI-WIN has also been added to the robust summary for reference.

Health Effects

EPA Comment

The submitter proposes to conduct a developmental toxicity study (deferred until 2003) and an in vitro chromosomal aberration assay. Adequate data are available for the acute and genetic (bacterial) toxicity endpoints. The submitter notes that neither repeated dose toxicity nor reproductive toxicity data are needed because Methyl DVEster is a "closed system intermediate" as defined by EPA for the HPV Challenge Program.

Reproductive and Repeat Dose Toxicity

The Guidance for Testing Closed System Intermediates for the Challenge Program http://www.epa.gov/chemrtk/guidocs.htm allows for a reduced testing proposal provided certain criteria are met. The information required to judge a "closed system intermediate" claim must address the following:

I. Site information.
    A. Number of sites.

B. Basis for "closed process" conclusion at each site.
    1) Process description.
    2) Monitoring data showing no detection.
    3) In the absence of monitoring data, the basis for believing that releases do not occur.

C. Data on "presence in distributed products."

II. Information on transport (mode, volume, controls, etc.)

III. A data search showing that the chemical is not present in other endproducts.

EPA believes that the submitter has generally addressed the criteria described above. However, EPA requests clarification on a number of points. The submitter indicates that Methyl DVEster is used on site to manufacture other substances. However, it is not clear if the monitoring information also pertains to those activities. The submitter indicates that the average concentration in the wastewater stream is 678 ppm. It is not clear from the description if this concentration is in the wastewater stream sent to the on-site carbon bed treatment facility or the wastewater stream sent to the POTW after carbon bed treatment. The submitter supplied a process diagram for the one off-site facility processing the substance operated by Syngenta Crop Protection, Inc. In the test plan the off-site facility is identified as a Zeneca facility. The submitter has confirmed they are one in the same. Consequently, provided the submitter addresses the above points to satisfy the standards for meeting the "closed system intermediate" claim, repeat dose and reproductive toxicity tests do not need to be conducted.

FMC Response

1. The wastewater monitoring and industrial hygiene data presented in the previously submitted closed system intermediate documentation are for the Methyl DVEster manufacturing location only.

Methyl DVEster is consumed as a reactant when used to manufacture other substances, therefore, the other on-site manufacturing locations only monitor for low level impurities in the final products. These low level impurities have been previously described in the Presence in Distributed Product and in End Use Products section of the closed system intermediate documentation.

2. The average concentration of Methyl DVEster in the wastewater stream prior to on-site carbon bed treatment is 678 ppm. Sampling for Methyl DVEster after carbon bed treatment is not required as part of the permit to discharge to the POTW, however, lower concentrations would be expected after treatment.

Ecological Effects (fish, daphnid, and algal toxicity).

EPA Comment

Adequate existing data are available for these endpoints. However, the robust summary for algae indicates that there are 96-hour data available and these data need to be submitted.

FMC Response

The robust summary for algae has been revised to include the 96-hour data.

FMC Response to EPA Comments on the CYCLOPROPANECARBOXYLIC ACID, 3(2,2-DICHLOROETHENYL)-2,2-DIMETHYL-, METHYL ESTER Robust Summaries

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

EPA Comment

Transport/distribution. The submitter needs to provide the in-put values for the fugacity calculation.

FMC Response

The robust summary has been revised to include all input values for the fugacity calculation. The only user input in the model is the structure of the molecule. All other input values are calculated by EPI-WIN. An explanation of the fugacity model used in EPI-WIN has also been added to the robust summary for reference.

Ecological Effects (fish, daphnid, and algal toxicity).

EPA Comment

Algae. In addition to the 120-hour data the 96-hour data should also be reported for comparison purposes with other studies.

FMC Response

The robust summary for algae has been revised to include the 96-hour data.